DEPARTMENT OF HEALTH AND HUMAN SERVICES

Reference: BK960002
Product: ACT Buoyant Density Solution

12 AUG 1996

Frank H. Valone, M.D.
Vice President, Medical and Regulatory Affairs
Activated Cell Therapy, Incorporated
291 North Bernardo Avenue
Mountain View, CA 94043

Dear Dr. Valone:

The Center for Biologics Evaluation and Research has completed its review of your Premarket Notification [510(k)] of intent to market the above device and we have determined that the device is substantially equivalent to devices marketed in interstate commerce prior to enactment of the Medical Device Amendments, May 28, 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug and Cosmetic Act.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls may be broadened to include additional regulations relating to restricted devices, records and reports, and others.

This letter should not be construed as approval of your device, rather it indicates that sufficient information has been submitted to determine that the device is substantially equivalent to another device previously marketed in interstate commerce.

Sincerely yours,

Jay P. Siegel, M.D., FACP
Director
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research